

REMARKS

I. The Interview

Applicant thanks Examiner Maria Marvich and her supervisor for the courtesy of the telephonic interview kindly granted on March 8, 2005 to Applicant's agents Greta Noland and Sharon Sintich. During the interview, the rejections under 35 U.S.C. § 112, first paragraph and the data provided in the "Declaration of Jeffery S. Bartlett under 37 C.F.R. § 1.132" filed on May 24, 2004 were discussed.

II. The Outstanding Rejections

In the latest Action, claims 1-10, 17-18, 21-23 and 25-26 were rejected under 35 U.S.C. § 112, first paragraph, because the specification was asserted to not "reasonably provide enablement for ANY AAV vector other than AAV2 with insertions at corresponding site." Applicant traverses this rejection and asserts that the rejected claims are enabled for the reasons set out in the responses filed May 24, 2004 and November 12, 2004.

Claims 1-10, 17-18, 21-23 and 42-44 were also rejected under 35 U.S.C. § 112, first paragraph, on the asserted basis that the specification does not provide adequate written description for the claimed subject matter. The Examiner stated that "the genus of AAV vectors with corresponding insertion sites had not been disclosed and a person of skill in the art would not have been able to envision the claimed genus given the state of the art at the time of filing." Applicants traverse this rejection and assert that the specification adequately describes the claimed genus in view of the knowledge in the art at the time of filing as described in detail in the responses filed May 24, 2004 and November 12, 2004.

At page 8 of the Action, claims 1-10, 17-18, 21-23 and 42-44 were rejected under 35 U.S.C. § 112, first paragraph, for that stated reason that the recited genus of "an amino acid insertion" is not adequately described in the specification. Applicants traverse this rejection as the specification teaches a representative number of peptides for insertion into the capsid protein of AAV vectors. In particular, Table 1 in the specification (pages 11-18) provides eight different peptides that were inserted into the VP1 capsid at the positions recited by the pending claims. These insertions of various sequence and size did not affect the viral particle production or infectability. Moreover, the specification teaches various

types of peptides that Applicant contemplates as encompassed by the claimed invention. These peptides include therapeutic peptides (page 6, lines 1-11), immunogenic peptides (page 6, lines 12-21), peptides that confer tropism (page 6, lines 22 through page 7, line 8), BAP peptides (page 7, lines 9-19), peptides that direct cellular trafficking (page 7, lines 20-26) and peptides that confer cellular uptake (page 7, line 27 through page 8, line 2). Therefore, the specification adequately describes a representative number of species of amino acid insertions and one of skill in the art will understand which types of peptides would be encompassed by the claims.

III. Amendments

In order to expedite prosecution, Applicant has amended the claims as noted at pages 2-6 of this paper. First, the claims have been amended to recite an AAV2 vector comprising an insertion at a specified position in the AAV2 VP1 capsid. Second, Applicant has amended claims 1 and 4 to recite "a peptide insertion." Exemplary support for this amendment is detailed above where the claim limitation "an amino acid insertion" is discussed.

CONCLUSION

Applicants respectfully submit that the rejections under 35 U.S.C. § 112, first paragraph should not be applied to the amended claims and that claims 1-10, 17, 18, 21-23, 25, 26 and 42-44 are in condition for allowance. Early notice thereof is requested.

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Respectfully submitted,

By 

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